ASR GROUP | FLORIDA CRYSTALS | Domino SUGAR | C&H

Domino Foods, Inc.
Specialty Ingredients

SUGAR PLAYS A VITAL ROLE AS A FUNCTIONAL INGREDIENT

Domino Specialty Ingredients – a vertically integrated company – uses experience and expertise in developing sugarcane from the source raw material to deliver pioneering products

Sugarcane Field

LONGTIME VALUED INGREDIENT

Since the days when a "spoonful of sugar" was recommended to get children to take their medicine, sugar has been a valued excipient for the pharmaceutical industry.

Today, specially processed grades of sugars are used not only to impart sweetness but also to bring many other vital functionalities to pharmaceutical and nutraceutical formulations. Domino – a name recognized for more than a century by consumers for filling sugar bowls, and baking – is known as the leading source of technological innovation sugars for product applications that provide solutions, reduce production costs and improve end-product performance.

UNIQUE BENEFICIAL PRODUCT

Our years of expertise and product development have had a dramatic impact on the trend toward direct compression tableting. DiPac® Direct Compacting & Tableting Sugar is a unique co-crystallized product that provides direct compressibility, enhanced flowability, solubility and dispersion. Additionally, we offer more than a dozen distinct grades of National Formulary Sugars for coatings, syrups and other applications.

CO-CRYSTALLIZATION PRODUCES MICROSCOPICALLY SUPERIOR SUGARS

Domino's discovery of co-crystallization and development of its Di-Pac® product represented a revolution in the use of sugar as an excipient

CO-CRYSTALLIZATION TECHNIQUE

Domino reinvented sugar when it discovered an alternative crystallization technique. Known as co-crystallization, this technique involves spontaneous crystallization of a supersaturated sucrose solution and a second ingredient by agitating it while cooling. This co-crystallization process produces an agglomerated sponge-like structure, with vastly increased surface area. The second ingredient is an integral part of the structure's matrix.

EXCIPIENT WITH REMARKABLE QUALITIES

In short, an exciting excipient was born. This innovative product, known as Di-Pac® Direct Compacting & Tableting Sugar, displays a remarkable array of qualities that are desirable for excipients used in tableting. In fact, as drug companies move away from the old wet granulation technique and its attendant problems, they often discover that Di-Pac is the practical solution. There is no stratification or clumping of active ingredients, just consistent quality in the finished product. The most striking attribute is high compressibility. In fact, if you pinch a small amount of Di-Pac between your thumb and forefinger and press moderately, it will form a cohesive conglomerate. For the direct compression process, in which lowering pressure improves production efficiency, this quality alone makes Di-Pac a smart choice.

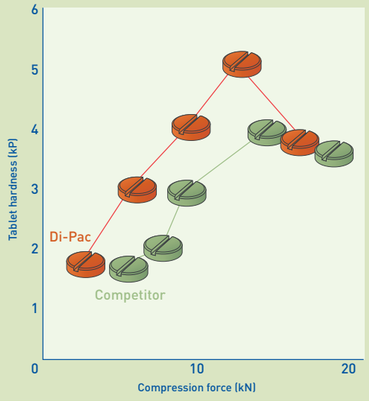
DESIRABLE CHARACTERISTICS AND APPLICATIONS

Di-Pac is highly inert and will not react with most active ingredients, in part because unlike other sugar-based excipients on the market, it contains no invert sugar and has less than 1% moisture. Eliminating another problem encountered with invert, Di-Pac has very low hygroscopicity, which means it remains free flowing in processing and helps extend the shelf life of the end product for applications including tableting and soft chews. Because Di-Pac is porous, it provides uniform blending and even distribution of the active ingredients, which improves dispersion. And, as a readily soluble excipient, it contributes to the solubility of the ingredients it carries, reducing or eliminating the need for disintegrants.

COMPRESSION FORCE VS. HARDNESS

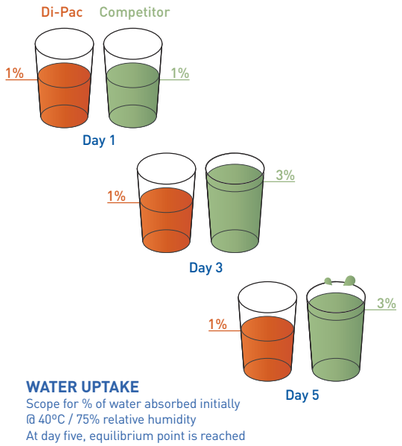
Compared to other compressible excipients, Di-Pac® requires less compression force to make harder tablets. This reduces energy and equipment maintenance costs.

TABLET HARDNESS
20% blend acetaminophen tablet (100mg)



HYGROSCOPICITY

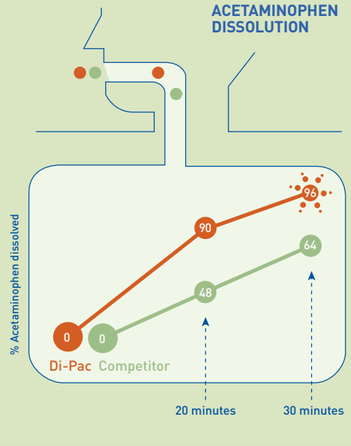
Di-Pac is one of the least hygroscopic direct compression excipients available. This is because its crystalline structure is in the beta prime configuration, which is the most stable. Since moisture pickup can lead to degradation of actives, tablets made with Di-Pac assure potency throughout shelf life, avoiding use of unnecessarily high levels of actives.



WATER UPTAKE
Scope for % of water absorbed initially
@ 40°C / 75% relative humidity
At day five, equilibrium point is reached

DISSOLUTION WITH 20% ACETAMINOPHEN

The USP test method specification for acetaminophen dissolution is 75% dissolved at 30 minutes. Di-Pac easily surpasses this standard, reaching a Q of 90% by 20 minutes. This means that an active ingredient carried by Di-Pac would be available more quickly, without any disintegrant.



DI-PAC® OFFERS SUPERIOR PERFORMANCE IN THREE KEY CATEGORIES

Performance characteristics demanded by applications for sugar as functional ingredients are all enhanced with Domino's product innovation

Sugarcane Field

Sugarcane Fields

DIRECT COMPRESSION VS. WET GRANULATION

The most commonly used technique is not always the simplest or most effective

ADVANTAGE OF DIRECT COMPRESSION

Although wet granulation is the most commonly used technique for manufacturing compressed tablets, it poses a number of problems that can be avoided by using the direct compression method instead.

Overall, wet granulation is a more complex, time-consuming and labor-intensive process, whereas direct compression is simpler, streamlined and more cost-effective.

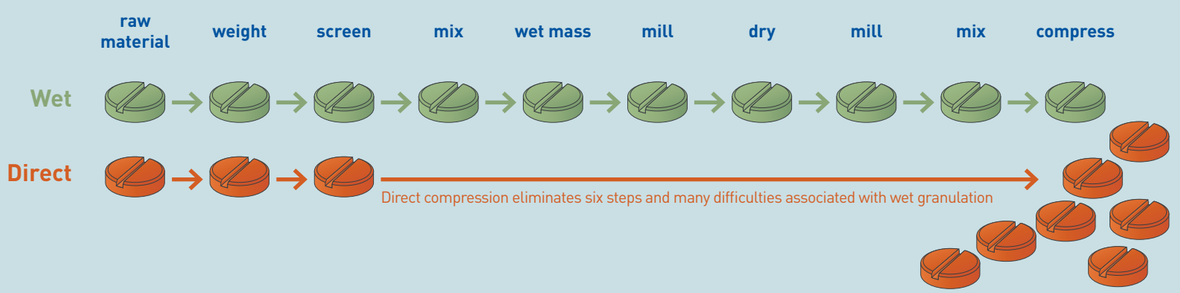
DIFFICULTIES WITH WET GRANULATION

In wet granulation, the blended dry ingredients must be wetter with a liquid solvent to convert the powder to a wetted mass, which must then go through a screening and milling process. Next, the material is dried to remove the solvent, followed by more screening, milling and mixing, and finally, compression. Direct compression eliminates the steps from wetting through drying.

Volatile solvents used in wet granulation posed additional problems. Special attention must be paid to work areas to maintain safe conditions. This usually involves special ventilation to reduce direct toxic effects and keep volatile concentrations below the explosion threshold. It also usually requires electrical grounding of all equipment and the use of explosion-proof or explosion-resistant motors. Drying equipment must employ a high rate of airflow to keep solvent vapor levels below the explosion limit, and exhausted vapors may need to be recovered or combusted in order to meet environmental regulations.

ELIMINATING DIRECT COMPRESSION PROBLEMS

Certain problems sometimes experienced with direct compression – stratification of active ingredients, noncompressibility of active ingredients in large-dose formulations, and active ingredient clumping due to static charge – can be eliminated by using Di-Pac®, produced through our patented co-crystallization technology.



A CAREFULLY ENGINEERED RANGE OF NATIONAL FORMULARY (NF) SUGARS

Domino's leadership in the development of sugar for functional ingredients in pharmaceuticals has resulted in valuable choices

Sugarcane Field

ECONOMICAL AND EFFICIENT SOLUTIONS

There are numerous applications for sugars in the manufacture of pharmaceuticals and nutraceuticals, and our range of National Formulary (NF) Sugars enables you to choose a sugar that is precisely right for each formulation.

Whether coating tablets, making syrups, tableting or mixing nutritional formulas, dry blends, gels, creams, or soft chews – you will find an economical and efficient solution in our NF product line, which includes grades from confectioners' to large grain sugars. No matter which you choose, you can be assured of compliance with National Formulary Monographs. Each order is accompanied by a Certificate of Analysis.

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For samples of Di-Pac®, NF Sugar products, information about global availability and compliance, or to speak to a technical customer service expert, please contact:

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